

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Appellants: | Dekkers, et al. |) | |
| | |) | Group Art Unit: 1713 |
| Serial No.: | 10/797,975 |) | |
| | |) | |
| Filed: | March 11, 2004 |) | Examiner: William K. Cheung |
| | |) | |
| For: | BIOCIDAL COMPOSITIONS |) | |
| | AND METHODS OF MAKING |) | |
| | THEREOF |) | |

VIA ELECTRONIC FILING

Assistant Commissioner for Patents
P.O. Box 1450
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APPEAL BRIEF

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is The General Electric Company.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to Appellants, Appellants' legal representatives, or assignee that will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-20 are pending in the application. Claims 1-19 stand finally rejected, Claim 20 stands withdrawn, and no claims are allowed. Claims 1-19, as they currently stand, are set forth in Appendix A. Appellants hereby appeal the final rejection of Claims 1-19.

IV. STATUS OF THE AMENDMENTS

No amendments have been filed subsequent to the final rejection dated April 26, 2006. All prior amendments have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a method of making a shaped article, comprising thermoforming an article (§ 0014) comprising an exterior surface comprising an inorganic biocidal agent (§ 0017) and a first thermoplastic resin (§ 0033) to form the shaped article (§ 0082), wherein the shaped article has improved biocidal activity (§ 0007) compared to the unshaped article (§ 0088).

Appellants have discovered that, unexpectedly, an article that is thermoformed to form a shaped article has superior biocidal activity over an article that is not thermoformed. As shown in Example 1 and Table 1 of the present application, thermoforming a biocidal article improves the silver release and thus the biocidal activity of the article. (page 32, line 25 to page 33, line 12) The middle and side of the thermoformed article had a silver release of 24 and 20 ppb, respectively, which is about 3-fold greater than the article that was not thermoformed, which had a silver release of 7.4 ppb.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1 – 19 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent No. 4,775,585 to Hagiwara, et al. (“Hagiwara”) in view of U.S. Patent No. 5,939,153 to Valyi (“Valyi”), and further in view of U.S. Patent No. 5,064,599 to Ando, et al. (“Ando”).

VII. ARGUMENT

Claims 1-19 are Non-Obvious over Hagiwara in view of Valyi and further in view of Ando.

The present invention relates to thermoforming an article comprising a thermoplastic resin and an inorganic biocidal agent. (page 2, ll. 6-9)

The present invention is based on Appellants’ discovery that thermoformed articles exhibit unexpectedly superior inorganic biocidal agent release properties over unshaped articles. Appellants have discovered that when an article or multi-layer article is formed by extrusion, milling, or molding, for example, a thin film of polymer that is different in composition from the bulk of the article is formed on the exterior surface of the article. This thin film or skin can be as thin as a few angstroms up to about 4 millimeters, yet the presence of this film can inhibit the biocidal activity (i.e., biocidal metal release and/or anti-microbial efficacy) of the articles and/or multi-layer articles. (page 4, ll. 20-28) Thermoforming, i.e., simultaneously heating and forming the article or multi-layer article, results in stretching of the surface of the article. It is believed that this surface stretching reduces the thickness of the above-described thin film on the surface of the article, and results in improved silver release and improved anti-microbial efficacy of the thermoformed articles. (page 5, ll. 26-30)

As shown in Example 1 and Table 1 of the present application, thermoforming a biocidal article improves the silver release and thus the biocidal activity of the article. (page 32, line 25 to page 33, line 12) The middle and sides of the thermoformed article had a silver release of 24 and 20 ppb, respectively, which is about 3-fold greater than the article that was not thermoformed, which had a silver release of 7.4 ppb. No improvement was observed at the edge of the thermoformed article, which had a silver release of 6.9 ppb. These observations are consistent with the hypothesis that the stretching of the article during thermoforming, which is expected to be more pronounced at the middle and side of the article than at the end, affects the thin film of polymer on the surface and results in improved inorganic biocidal agent release.

The Examiner has combined three references to provide all elements of the Appellants' claimed invention. Hagiwara is directed to a polymer article containing zeolite particles. (See Abstract) The polymer article is produced, for example, by admixing bactericidal metal ion-containing zeolite particles with an organic polymer prior to molding, or by mixing a molded organic polymer containing a zeolite with a metal ion salt to form a metal ion-containing zeolite *in situ*. The Examples disclose molding the zeolite-containing polymer into fibers and yarns by a process of melting, spinning, and drawing. (Col. 13, ll. 23-25) Example 1 discloses that each knitted fabric was washed 50 times and then subjected to an evaluation of an antibacterial effect. (Col. 13, ll. 28-33) Hagiwara fails to disclose thermoforming the molded article.

Valyi is directed to lined beverage containers. Valyi discloses a process for forming a multilayered plastic article and multilayered plastic preform and container, wherein a polyepoxide or a liquid crystal polymer in the liquid form is applied to a substrate in a thickness which varies over the extent of the substrate to form a multilayered substrate, forming a tubular liner from said multilayered substrate, and coating the tubular liner with an outer layer. (Abstract) The multilayer structure may be thermoformed. Valyi further discloses that the polyepoxides, especially the epoxy-amine thermosetting resins, are favored because the polyepoxides do not have to be shielded from beverage contact in a beverage container. (Col. 3, ll. 9-20)

Ando is directed to conjugated fibers comprising a low-melting point component and a high-melting point component, wherein the low-melting point component comprises zeolite particles. (See Abstract) Upon heating, the low-melting point component spreads to increase the surface area and cause more zeolite particles to be exposed, which yields higher antibacterial activity in a fiber article produced from the conjugated fibers. (Abstract; Col. 8, ll. 31-33) Ando fails to disclose thermoforming the molded article.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a *prima facie* case of obviousness, i.e., that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5

U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

The Federal Circuit has recently held

[T]o establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. In practice, this requires that the Board explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.

In re Kahn, 441 F.3d 977, 986, 78 U.S.P.Q.2d 1329 (Fed. Cir. 2006) (internal citations and quotation marks omitted). Similarly, in *In re Oetiker*, the Federal Circuit held that “the combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness.” *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992).

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. Appellants maintain that one of ordinary skill in the art would not be motivated to combine the references in the manner proposed by the Examiner. Appellant further submit that the Examiner has improperly used hindsight gleaned from Appellants’ own disclosure to piece together elements from non-analogous sources to arrive at Appellants’ invention.

Hagiwara teaches polymers containing zeolites, but fails to teach thermoforming to improve biocidal metal release. In order to find a reference for thermoforming, the Examiner combines the brief reference in Hagiwara to a container with a portion of Valyi, which is directed to a gas barrier liner for the inside wall of a beverage container. The Examiner has stated that because Hagiwara “clearly discloses processes that are suitable for making containers, it would have been obvious to one of ordinary skill in the art to appreciate the thermoforming techniques for making the containers of Hagiwara et al.” (Advisory Action dated June 30, 2006, page 2) Appellants submit that one of ordinary skill in the art would not be motivated to combine a reference primarily directed to biocidal fibrous articles with a reference directed to a beverage container, and that there is no expectation of success for the use of the thermosetting technique of Valyi in the compositions of Hagiwara. Appellants also submit that Valyi expressly discloses that the useful materials for the liner are limited only to polyepoxides, preferably epoxy-amine thermosetting resins. (Valyi, Col. 3, ll. 9-20) In contrast, Hagiwara fails to

disclose polyepoxides. One of ordinary skill in the art would not be motivated to modify Hagiwara, which teaches a variety of thermoplastic polymers, but not polyepoxides, with a thermoforming technique that is taught to be useful for only for polyepoxides. In addition, one of ordinary skill in the art would be aware of the limitations of shaping a thermosetting polymer by thermoforming since a thermosetting polymer, such as the polyepoxides of Valyi, would not be as flowable as thermoplastic polymers.

In the Advisory Action dated June 30, 2006, the Examiner rejected Appellants' argument that there is no motivation to combine Valyi with Hagiwara because "Valyi is directed to a multilayer structure comprising polyepoxides." (Advisory Action dated June 30, 2006, page 2) The Examiner further stated that "applicants fail to recognize that the claims as written do not exclude the multilayer structure of Valyi." Appellants respectfully submit that Valyi discloses a multilayer article comprising a polyepoxide rather than simply a multilayer article. Appellants further submit that the assertion regarding what the claims do not exclude fails to address whether there is motivation to combine the references. One of ordinary skill in the art simply would not combine the teachings of Hagiwara and Valyi because of the differences in the properties of the polymers described in these references.

Appellants further submit that Valyi teaches that both thermoforming and blow-molding yield similar results and either process can be used to shape an article depending on whether the original form is a sheet for thermoforming or a tube for blow-molding. (Col. 4, ll. 6-8) Therefore, upon reading Valyi, one of ordinary skill in the art would not be motivated to select thermoforming as compared to other methods of shaping an article. While one might try thermoforming an article such as that disclosed in Hagiwara, this is not the standard for patentability. A finding of "obvious to try" does not provide the proper showing for an obviousness determination. The requirement for a determination of obviousness is that "both the suggestion and the expectation of success must be founded in the prior art, not in Appellant's disclosure" (emphasis added). *In re Dow Chem.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). An Examiner, then, cannot base a determination of obviousness on what the skilled person in the art might try or find obvious to try. Rather, the proper test requires determining what the prior art would have led the skilled person to do. Finally, Appellants dispute that Valyi provides the motivation to use a thermoforming process to prepare a container

containing an inorganic biocidal agent because Valyi fails to teach or suggest that its liner has biocidal activity or that thermoforming improves the biocidal activity of its liner.

The Examiner relies on Ando for teaching that heating improves the exposure of zeolite particles on an article surface. The teaching of Ando, however, is limited to compositions that contain a low-melting point component and a high-melting point component. Ando teaches that for fibrous compositions with a low-melting point component and a high-melting point component, upon heating, the low melting point component of the resins spreads to cause more zeolite particles to be exposed on the surface. Example 1 disclose heating the fibrous article containing a low-melting point component and a high-melting point component at 150° C for one minute using an oven with a hot air circulation to melt the low-melting component. The low-melting point component spreads and zeolite particles were seen on the surface. (Col. 9, ll. 42-49) Ando, therefore, discloses heating sufficient to melt only the low-melting point component.

In contrast, the present invention is directed to thermoforming, not simply heating:

Thermoforming comprises simultaneously heating and forming the article or multi-layer article, e.g., an extruded sheet, into the desired shape such as in a mold. Either vacuum or pressure against the mold may be used to form the article or multi-layer article.

(page 31, ll. 21-24) Ando fails to disclose thermoforming, or simultaneously using heat and pressure to form an article.

As is known to those of ordinary skill in the art, thermoforming involves heating an article above its core temperature. The heating regimes disclosed by Ando would fail to achieve the core temperatures required for thermoforming. Because the low-melting point component (polyethylene) of Ando has a relatively high specific heat (0.55 at 20° C and 0.7 at 120° C) and would therefore require a relatively high amount of heat energy to increase its core temperature to the thermoforming temperature. As one of ordinary skill in the art would understand, convection heating, such as in a recirculating hot air oven, is a relatively slow method of heat transfer. Therefore the 1 to 2 minute heating regime disclosed by Ando would be insufficient to heat the core to a thermoforming temperature for the low-melting point component, let alone the high melting point component. Ando therefore fails to teach or suggest thermoforming and thus cannot teach the advantages of thermoforming as disclosed in the present application compared to the simple heating disclosed in Ando.

Appellants further submit that one of ordinary skill in the art would not be motivated to modify Ando to provide thermoforming an article because Ando is directed to melting a low melting point component comprising zeolite particles. In the Advisory Action dated June 30, 2006, the Examiner rejected Appellants' argument that there is no motivation to combine Ando with Hagiwara because "Ando et al. teach a composition comprising low melting components that spread to expose zeolite particles." (Advisory Action dated June 30, 2006, page 2) The Examiner disagreed, stating that

[T]he teachings in Ando et al. are merely to affirm that zeolite particles can be exposed upon heating. Applicants must recognize that the zeolite in Hagiwara et al. will be exposed upon heating during the thermoforming with or without the teachings of Ando et al. Nevertheless, the reference to Ando et al. clearly show[s] that the argued "unexpected" results are indeed "expected."

(Advisory Action dated June 30, 2006, page 2)

Appellants respectfully disagree with the Examiner's arguments. First, Appellants respectfully submit that the Examiner has oversimplified the teaching of Ando, which discloses melting a low-melting point component to expose the zeolite particle contained therein. Ando does not teach a general principle that zeolite particles can be exposed upon heating, as stated by the Examiner. Further, the present claims do not require a low-melting point component and a high-melting point component as required by Ando.

Second, Appellants respectfully submit that the Examiner has not provided any rationale as to whether there is motivation to use thermoforming, as opposed to heating, to improve the biocidal activity of an article. In fact, the Examiner appears to concede that Ando fails to provide motivation for thermoforming since the Examiner has stated that zeolite particle will be exposed upon heating during thermoforming "with or without the teachings of Ando et al."

Third, the Examiner fails to provide a rationale to establish a *prima facie* case of obviousness other than his conclusory statement that zeolite particles will be exposed upon heating. (Advisory Action dated June 30, 2006, page 2) Appellants respectfully submit that this statement is demonstrably incorrect. The present claims require thermoforming an article, which involves simultaneous heating and forming. As shown in Example 1 and Table 1 of the present application, the middle and sides of the thermoformed article had a silver release of 24 and 20 ppb, respectively, which is about 3-fold greater than the article that was not thermoformed, which had a silver release of 7.4 ppb. No improvement was observed at the edge of the

thermoformed article, which had a silver release of 6.9 ppb. (page 32, line 25 to page 33, line 12) If it were true that zeolite particles would be exposed upon heating, then one of ordinary skill in the art would expect that the middle, side, and end would all exhibit improved silver release upon heating during thermoforming. These data clearly demonstrate that thermoforming an article, as opposed to simply heating, unexpectedly provides superior biocidal activity. Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because the only articulated rationale for combining Ando and Hagiwara is a conclusory statement that is demonstrably incorrect.

Fourth, Appellants respectfully submit that the Examiner's statements offer further evidence that the improved biocidal activity of a thermoformed article is indeed unexpected. Upon review of Ando, the Examiner concluded that zeolite particles would be expected to be exposed upon heating; however, Appellants' data clearly show that only the middle and sides, but not the edges, exhibited improved biocidal activity. Appellants respectfully submit that the results are unexpected, by definition, since they run contrary to the expectations cited by the Examiner.

"It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch* 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). Appellants maintain that the Examiner has used an improper standard in arriving at the rejection of the above claims under section 103, based on improper hindsight, which fails to consider the totality of Appellants' invention and to the totality of the cited references. More specifically, the Examiner has assembled elements from disparate references with motivation gleaned only from hindsight from Appellants' own disclosure to allegedly arrive at Appellants' invention. In doing so, the Examiner has failed to consider the teachings of the references or Appellants' invention as a whole in contravention of section 103, including the disclosures of the references, which teach away from Appellants' invention.

In order to make the combination proposed by the Examiner, one would have to focus on Hagiwara's passing reference to a container, ignore the list of useful polymers in Hagiwara, look to Valyi, which discloses various methods to manufacture containers from completely different polymers, and select only the teaching of thermoforming from Valyi to apply to the polymers of Hagiwara. There is no teaching in Valyi that thermoforming can or should be applied to the

polymers of Hagiwara, let alone polymers containing zeolites. Further, one would have to combine Ando for motivation, ignoring the specific teaching in Ando directed to combinations of low-melting point and high-melting point polymers, and generalize their teaching to heating of any zeolite-containing polymers. Ando does not teach thermoforming. One of skill in the art would not be motivated to make the combination suggested by the Examiner, and there certainly would be no expectation of success for the combination. Appellants respectfully submit that Examiner has used Appellants' own disclosure as an instruction manual to piece together selected elements from the teachings of the prior art.

For at least these reasons, the combined prior art teachings fail to provide a reasonable expectation of success by combining the references in the manner suggested by the Examiner. At best, this is only an "obvious to try" standard, which is not the proper standard for determining obviousness.

Even where a *prima facie* case of obviousness exists, obviousness may be rebutted by a showing of "unexpected results," i.e., comparative test data showing that the claimed invention possesses unexpectedly improved properties, or properties that the prior art does not have. *In re Dillon*, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990). The MPEP provides that objective evidence or secondary considerations such as unexpected results are relevant to the issue of obviousness and must be considered in every case in which they are present. MPEP § 2141(III). Examiners must consider comparative data in the specification, which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986); MPEP § 716.01(a). Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art, which is commensurate in scope with the claims. *See In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980); MPEP § 716.02(b) - § 716.02(e).

As shown in Example 1 and Table 1, thermoforming results in a shaped biocidal article with about a 3-fold improvement in biocidal metal (e.g., silver) ion release in the middle and sides of the article over a biocidal article which is not thermoformed. (page 33, ll. 5-12) The thermoformed article provides improved biocidal metal ion release and therefore improved biocidal activity. The biocidal activity is evidenced specifically in Table 3 where the biocidal efficacy improved dramatically with the amount of silver release. (page 35, ll. 1-5) The Examiner does not dispute the fact that the shaped article has improved biocidal activity

compared to the unshaped article. Appellants respectfully submit that the Examiner has failed to apply the *Graham* factors in the obviousness inquiry as required and failed to weigh objective evidence of nonobviousness. Specifically, Appellants respectfully submit that the Examiner has failed to consider the comparative data in the specification that demonstrate the unexpected results obtained by the present composition. Instead the Examiner has made a conclusory statement that the unexpected results are “expected.” (Advisory Action dated June 30, 2006, page 2; Office Action dated April 26, 2006, page 4) This conclusory statement appears to stem from an overstatement of the teachings of Ando, that is the allegation that Ando discloses that heating an article will cause the zeolite particle to be exposed on the surface. In the present case, the Examiner is incorrect. It is the thermoforming rather than just heating that improves the biocidal activity of the article. If heating alone were sufficient, the edges of the thermoformed article of the Appellants’ examples would have has similar increases in metal release to the middle and sides. Appellants respectfully submit that the unexpected results disclosed in Example 1 would successfully rebut a *prima facie* case of obviousness, if it existed.

In summary, Claims 1-19 are non-obvious over the art of record. For the reasons cited above, Appellants respectfully submit that all of the claims are allowable and the application is in condition for allowance. Appellants respectfully request reversal of the outstanding rejections and allowance of this application.

In the event the Examiner has any queries regarding the submitted arguments, the undersigned respectfully requests the courtesy of a telephone conference to discuss any matters in need of attention.

If there are any additional charges with respect to this Appeal Brief, please charge them to Deposit Account No. 50-3621.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. (Original) A method of making a shaped article, comprising:
thermoforming an article comprising an exterior surface comprising an inorganic biocidal agent and a first thermoplastic resin to form the shaped article, wherein the shaped article has improved biocidal activity compared to the unshaped article.
2. (Original) The method of Claim 1, wherein the first thermoplastic resin comprises a homopolymer or a copolymer of a polycarbonate, a polyester, a polyacrylate, a polyamide, a polyetherimide, polyphenylene ether, or a combination comprising one or more of the foregoing resins.
3. (Original) The method of Claim 1, wherein the shaped article has biocidal activity effective to kill at least 50% of a pathogenic organism in contact with the exterior surface over a period of 24 hours at 25°C.
4. (Original) The method of Claim 1, wherein the article has a biocidal metal release factor of greater than 2.5 from an exterior surface
wherein biocidal metal release in parts per billion is measured by contacting 5 cm by 5 cm of the exterior surface with 40 milliliters of 0.8% weight/volume of sodium nitrate for 24 hours at 25° C to form a test solution, and measuring an amount of biocidal metal in the test solution in parts per billion, and
wherein the biocidal metal release factor is the amount of biocidal metal in the test solution in parts per billion divided by a product of a weight percent of the inorganic biocidal agent based on the total weight of the article and the weight percent of biocidal metal in the inorganic biocidal agent.
5. (Original) The method of Claim 4, wherein the biocidal metal release factor is greater than or equal to about 3.

6. (Original) The method of Claim 4, wherein the biocidal metal release factor is greater than or equal to about 4.

7. (Original) The method of Claim 1, wherein the exterior surface is in the form of a layer disposed on at least a portion of the article.

8. (Original) The method of Claim 7, wherein at least a portion of the shaped article comprises a second thermoplastic resin that is the same as or different than the first thermoplastic resin.

9. (Original) The method of Claim 8, wherein at least a portion of the article comprises an inorganic biocidal agent that is the same as or different than the inorganic biocidal agent in the exterior surface.

10. (Previously Presented) The method of Claim 3, wherein the biocidal activity is an anti-microbial efficacy that is greater than or equal to about 70% killing of an E. coli culture or a Staphylococcus aureus culture, measured by contacting the exterior textured surface of the article with the E. coli culture or the Staphylococcus aureus culture, incubating the article for 24 hours at 37°C, and determining the percentage of killing of the E. coli culture or the Staphylococcus aureus culture.

11. (Original) The method of Claim 10, wherein the anti-microbial efficacy of the shaped article is greater than or equal to about 95%.

12. (Original) The method of Claim 1, wherein the inorganic biocidal agent comprises a biocidal metal comprising silver, gold, copper, zinc, mercury, tin, lead, bismuth, cadmium, chromium, thallium, or a combination comprising one or more of the foregoing biocidal metals.

13. (Original) The method of Claim 12, wherein the inorganic biocidal agent is in the form of a metal salt, a hydroxyapatite, a zirconium phosphate, or a zeolite comprising at least one of the biocidal metals, or a combination comprising one or more of the foregoing forms.

14. (Original) The method of Claim 13, wherein the inorganic biocidal agent is a biocidal zeolite.

15. (Original) The method of Claim 14, wherein the biocidal zeolite comprises silver.

16. (Original) The method of Claim 2, wherein the first thermoplastic resin comprises a polycarbonate resin.

17. (Original) The method of Claim 1, wherein the inorganic biocidal agent is present at a concentration of about 0.1 wt% to about 20 wt% based on the total weight of the exterior surface.

18. (Original) The method of Claim 6, wherein the exterior surface layer has a thickness of about 5 micrometers to about 50 micrometers.

19. (Original) The method of Claim 1, wherein the shaped article reduces the growth of a pathogenic organism comprising *Bacillus cereus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Streptococcus feacalis*, *Salmonella gallinarum*, *Vibrio parahaemdyticus*, *Candida albicans*, *Streptococcus mutans*, *Legionella pneumophila*, *Fuso bacterium*, *Aspergillus niger*, *Aureobasidium pullulans*, *Cheatomium globosum*, *Gliocladium virens*, *Pencillum funiculosum*, *Saccharomyces cerevisiae*, a Herpes simplex virus, a polio virus, a hepatitis B virus, a hepatitis C virus, an influenza virus, a sendai virus, a sindbis virus, a vaccinia virus, a severe acute respiratory syndrome virus, or a combination comprising one or more of the foregoing organisms.

IX. EVIDENCE APPENDIX

There is no evidence submitted pursuant to 37 C.F.R. §1.130, 37 C.F.R. §1.131, or 37 C.F.R. §1.132 or any other evidence entered by the Examiner and relied upon by the Appellant in this appeal, known to the Appellants, Appellants' legal representatives, or assignee.

X. RELATED PROCEEDING APPENDIX

There are no other related appeals or interferences known to Appellants, Appellants' legal representatives, or assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.